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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,705	09/30/2003	Anna Maric Aguinaldo	A-71431-3	8128

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EXAMINER

HISSONG, BRUCE D

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 04/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/676,705	Applicant(s) AGUINALDO ET AL.	
	Examiner Bruce D. Hissong, Ph.D.	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-37 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

A. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-28 and 35, drawn to variant type I interferon proteins, and a pharmaceutical composition thereof, classified in class 424, subclass 85.4.
- II. Claims 29-34, drawn to nucleic acid molecules, vectors, and host cells, classified in class 435, subclass 69.1.
- III. Claim 36, drawn to a method of treating an interferon-responsive condition, classified in class 514, subclass 2.
- IV. Claim 37, drawn to a method of inhibiting interferon dimer formation, classified in class 436, subclass 537.

B. The inventions are distinct, each from the other because of the following reasons:

1. Inventions I and II are independent and distinct, each from each other, because they are products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged.

The polypeptide of group I and the polynucleotide of group II are patentably distinct for the following reasons: polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polypeptide and polynucleotide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. Furthermore, searching the inventions of groups I and II together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides is not coextensive. The inventions of groups I and II

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have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is also search burden in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides that would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers that had no knowledge of the polypeptide, but spoke to the gene. Searching, therefore, is not coextensive. As such, it would be burdensome to search the inventions of groups I and II.

2. Inventions III and IV are independent and distinct inventions, each from the other, because the methods are practiced with materially different process steps for materially different purposes, and each method requires a non-coextensive search because of different starting materials, process steps, and goals. In the instant case, the invention of group III is drawn to treatment of a patient in need of treatment, and has different process steps, starting materials, and goals than the invention of group IV, which is drawn to a method of inhibiting dimer formation between two proteins.

3. Invention I is related to inventions III and IV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product of group I can be used in a materially different process. For example, a variant interferon molecule of invention I can be used to raise antibodies specific for that variant interferon.

4. Invention II is unrelated to inventions III and IV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together.

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C. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

D. Additionally, groups I and II are subject to further restriction. It is noted that the claims are drawn to examination of at least one of a number of structurally distinct polypeptides. In order to be fully responsive, if Applicants elect group I, then Applicants are required to further elect a specific wild-type interferon from SEQ ID NOs 1-18, and a specific variant interferon from SEQ ID NOs 19-30. Furthermore, if Applicants elect a variant derived from SEQ ID NOs 1-14 (see claim 6), then Applicants are required to further elect a specific modification position and amino acid set forth in claims 9 and 27-28. Similarly, if Applicants elect SEQ ID NOs 15 or 16, the Applicants are required to elect one specific modification/amino acid from claims 10-11 or 20-21, respectively. Additionally, if Applicants elect group II, Applicants are required to further elect a variant interferon from SEQ ID NOs 19-30. This is NOT an election of species. The claimed peptide fragments are non-overlapping sequences and are structurally distinct chemical compounds, and are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such peptide is presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141. By statute "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant.....to elect that invention to which his claim shall be restricted." 37 CFR 1.142(a). See also 37 CFR 1.141(a). It is noted that search more than one of the claimed patentably distinct peptides represents a serious burden for the office.

E. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i). Applicant is also advised that the reply to this requirement, to be complete, must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

F. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce D. Hissong, Ph.D., whose telephone number is (571) 272-3324. The examiner can normally be reached M-F from 8:30am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, Ph.D., can be reached at (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BDH
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ROBERT S. LANDSMAN, PH.D.
PRIMARY EXAMINER